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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,614	03/01/2000	GAIL PETUNA RISBRIDGER	229752000800	6186

7590 12/28/2004

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/402,614

Applicant(s)

RISBRIDGER ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58,60-63 and 69-99 is/are pending in the application.
- 4a) Of the above claim(s) 1-57,63 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58,60-62,69-91 and 93-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Application/Control Number: 09/402,614
Art Unit: 1642

Page 2

Re: Risbridger *et al.*

Date of priority: 04/23/1997

Response to Amendment

The Amendment filed 09-30-2004 in response to the Office Action of 03-30-2004 is acknowledged and has been entered.

Claims 69-99 were newly added.

Claims 1-57, 63, 92 are withdrawn.

Claims 58, 60-62, 69-91, and 93-99 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restriction

The requirement for a species election (Action mailed 09-03-2001) between α N and α C is withdrawn (Claims 61 and 62). Thus, claim 61 is now newly pending.

Newly submitted claims 63 and 92 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 63 and 92 are drawn to

Art Unit: 1642

detecting changes in the expression levels of inhibin, i.e. mRNA which is independent and or distinct from the originally elected invention of detection inhibin protein levels.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 63 and 92 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Withdrawn:

The rejection of Claims 58, 60, and 62-63 as being anticipated by Teni *et al.* (Clinical Chemistry, Volume 35, No. 7, pages 1376-1379, 1989) is withdrawn. Applicants have provided evidence (Response, 09-03-04) and the art of record (Risbridger *et al.*, Jnl.Endocrinology, 1996, IDS) indicates that inhibins are structurally and functionally unrelated to prostatic inhibin-like peptide ("PIP"), also known as Beta-microseminoprotein.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Rejections Maintained:

Claims 58, 60, 62, remain rejected and new claims 61*, 69-91, 93-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of

Art Unit: 1642

screening for a mammal having prostate cancer comprising determining the amount of inhibin protein levels in both cancerous and corresponding normal prostate samples, wherein the presence of prostate cancer is verified by the *absence* of inhibin protein in the cancerous samples versus the normal samples, does not reasonably provide enablement for the broadly claimed invention for the reasons of record. Applicant's claims remain drawn to screening for those who are "predisposed" to develop prostate cancer. In their response, applicants did not address this limitation. As set forth previously, neither the specification nor any art of record indicates, suggests, or teaches that down-regulation or the absence of inhibin would lead one of ordinary skill in the art to predictably determine a predisposition to prostate cancer in an otherwise normal healthy mammal. Furthermore, newly independent claims 83 and 95 do not include the essential step of comparing inhibin levels such that the down-regulation and or absence of inhibin protein in the cancerous samples is observed. Thus, the rejection is maintained for the reasons of record.

* Previously withdrawn

New Objections/Rejections:

Claims 76 and 86 are rejected for reciting, "dimmer" as this appears to be a spelling error.

Claim 83 is objected to for reciting, "with a level *know*" which appears to be a grammatical error.

Claim 86 is objected to for reciting, "wherein level" which appears to be a grammatical error.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70-71 recite “the change” or “said change”. There is insufficient antecedent basis for this limitation from which claims 70-71 depend.

Claim 73 recites “said screening process”. There is insufficient antecedent basis for this limitation from which claim 73 depends.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

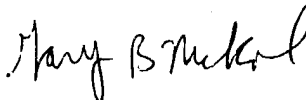
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN


GARY NICKOL
PRIMARY EXAMINER